

CHAPTER NO. 673**HOUSE BILL NO. 3513**

By Representative McMillan and Mr. Speaker Naifeh and Representatives Fowlkes, Overbey

Substituted for: Senate Bill No. 3392

By Senators Crutchfield, Graves, Miller, Burks, Dixon, Norris, Kurita

AN ACT to amend Tennessee Code Annotated, Title 10; Title 12; Title 20; Title 29; Title 33; Title 37; Title 39; Title 40; Title 41; Title 47; Title 49; Title 50; Title 53; Title 55; Title 56; Title 58; Title 63; Title 67; Title 68 and Title 71, relative to medical assistance and TennCare.

WHEREAS, the TennCare program has, since its beginning in January 1994, provided vital health care coverage to over one million poor uninsured and uninsurable Tennesseans; and

WHEREAS, the TennCare program, since its inception, has continued to see the overall cost of the program rise at an unsustainable rate; and

WHEREAS, McKinsey & Company, an independent, internationally known consulting firm, has thoroughly reviewed the TennCare program and determined that it is not financially viable in its current form. McKinsey & Company concluded, among other findings, that if the cost of the TennCare program continues to rise at its current rate, it will consume 91% of all new state revenues by the year 2008; and

WHEREAS, reforms must be instituted and controls must be placed on the overall expenditures of the TennCare program or the State will be faced with the dilemma of cutting back education and other areas of critical services provided to the citizens of Tennessee; and

WHEREAS, Governor Bredesen delivered a speech to a joint session of the House of Representatives and the Senate on February 17, 2004, in which he outlined a reform package to save TennCare; and

WHEREAS, Governor Bredesen's reform plan proposes fundamental changes to TennCare with the goal of preserving the underlying program and maintaining adequate benefits for as many enrollees, including currently eligible uninsured and uninsurable Tennessee citizens, as possible and practicable; and

WHEREAS, Governor Bredesen's TennCare reform plan is intended to stabilize TennCare expenditures at the current proportion of state revenues, and not to let expenses rise by the 10 percentage points projected by McKinsey & Company. Achieving this goal would result in freeing approximately \$1 billion in 2008 to be spent on other critical state needs, particularly education; and

WHEREAS, more than two dozen organizations representing education, business and industry, health care and other interests have endorsed Governor Bredesen's TennCare reform plan; and

WHEREAS, it is the clear intent and desire of the Tennessee General Assembly to endorse the reform plan and goals set forth by Governor Bredesen and to authorize the significant structural reforms that the Governor has said are necessary to save and sustain the TennCare program, including specific actions to get costs under control; and

WHEREAS, the TennCare program, in order to become a financially viable program, must take steps to stabilize expenditures through a variety of necessary measures, which may include but are not limited to, elimination of covered benefits or limitations on the scope, intensity, or duration of such benefits, implementation of cost sharing requirements for enrollees, including the Medicaid population, aggressive methods of controlling pharmaceutical costs, including the use of reference pricing, prior authorization, step therapy requirements, exclusion from coverage of drugs, mandating the use of generic drugs or therapeutic equivalent drugs, and elimination from eligibility of non-mandatory categories of enrollees. Other measures may include new programs that help to more efficiently and effectively provide medical services, new initiatives that utilize the latest technology in health care services, ongoing, and objective expert review processes; and

WHEREAS, the State of Tennessee, in taking such steps to control costs, may also determine that the State's best interests are served by providing a "Safety Net Program" for certain individuals who need access to non-emergency medically necessary covered health care services but do not have the ability to meet cost sharing requirements or who have exhausted the benefits for which they are eligible; and

WHEREAS, the steps to keep TennCare viable will require the best efforts and cooperation of the State, providers, advocates, TennCare members, and all other groups that value this program and want to ensure its continuation on behalf of all the Tennesseans that the TennCare program serves; and

WHEREAS, because of the negative effect of TennCare fraud and abuse on the people of the State of Tennessee and those individuals who need medical assistance, the General Assembly declares it to be public policy of the State of Tennessee that TennCare fraud and abuse be identified and dealt with aggressively and appropriately; and

WHEREAS, one of the purposes of this act is to create the Office of TennCare Inspector General, which will be a new division that will focus solely on the prevention and detection of fraud and abuse in the TennCare program; and

WHEREAS, the creation of the Office of TennCare Inspector General is necessary and important because TennCare fraud and abuse undermines the financial stability of the State and the public faith in the TennCare program, and deprives enrollees of quality health care services; now, therefore,

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Section 71-5-102, is amended by adding as a new subsection (d) the following:

(d) The bureau of TennCare shall have the authority to develop and implement initiatives or program modifications to control the costs of the TennCare program to the extent permitted under federal law and the TennCare waiver. Such cost-saving measures may include, but are not limited to, the elimination of covered benefits or

limitations on the scope, intensity, or duration of such benefits; implementation of cost sharing requirements for enrollees, including the Medicaid population; increases in cost sharing requirements for the expansion population; enforcement of cost sharing requirements through denial of service for failure to meet co-payment requirements with alternative access to medically necessary care through established safety net providers; enforcement of collection of required co-payments by providers; reassignment of enrollees into different eligibility categories; restrictions on eligibility for non-mandatory Medicaid or waiver expansion categories; and the elimination from TennCare eligibility of some or all of the non-mandatory Medicaid or waiver expansion categories. The bureau of TennCare may implement a premium-assistance initiative for persons disenrolled from TennCare. The bureau of TennCare shall also be authorized, in establishing or modifying benefits or cost sharing requirements, to define, through rules and regulations, categories of eligible enrollees who may be exempted from some or all benefit limits or cost sharing requirements, along with any requirements that must be met by such enrollees to prove or maintain exempted status. The bureau of TennCare shall have all such authority to control costs notwithstanding any other state law to the contrary.

SECTION 2. Tennessee Code Annotated, Section 71-5-107, is amended by adding the following new subsections (e), (f), and (g):

(e) The bureau of TennCare shall have the authority to implement a comprehensive disease management program for certain enrollees of the TennCare program to the extent permitted under federal law and the TennCare waiver. The bureau, through its authority to promulgate rules and regulations, may identify enrollees eligible to participate and the disease categories to be included in the comprehensive disease management program. The bureau, also through its authority to promulgate rules and regulations, may put in place requirements regarding the continued participation of enrollees in the program.

(f) Subject to the availability of funding earmarked for such programs in the General Appropriations Act and to the extent permitted under federal law and the TennCare waiver, the bureau of TennCare shall have the authority to create in whole or in part and administer a program to be named "The TennCare Safety Net" which will provide two different components to assist eligible TennCare enrollees:

(1) Certain medical providers in Tennessee shall provide non-emergency health care services without co-payment requirements to certain specified TennCare enrollees. Such services are intended to include only services that are both medically necessary and within the scope of TennCare benefits for the particular enrollee but for which the enrollee cannot meet the co-payment requirements. Through its authority to promulgate rules and regulations, the bureau of TennCare will identify the parameters of this component of the TennCare Safety Net program, including which enrollees are eligible to participate in this program, allowable benefits under the program, designation of both urban and rural providers who participate in this program, and a funding methodology pursuant to which such providers shall be compensated.

(2) (A) A TennCare Foundation will be established that will accept and review applications for medical assistance submitted on behalf of certain specified TennCare enrollees. The members of the Foundation shall be appointed by the Governor, who shall determine the size and composition of the

Foundation's membership. The Governor should strive to ensure that the membership is representative of the State's geographic and demographic composition with appropriate attention to the representation of women and minorities. Terms for the members will be staggered and the length of terms will be detailed by the Governor in making initial or subsequent appointments. The Governor shall appoint the chair and vice-chair. For the purposes of administration and availability of records, the TennCare Foundation shall be located within the bureau of TennCare. Staff assistance shall be provided by the bureau of TennCare or by another entity, should the Governor so determine. At the discretion of the Governor, the Foundation may be placed within another appropriate agency, may create or be reconstituted as a non-profit entity, or may be terminated at any time.

(B) Applications for medical assistance from the Foundation are not intended, and should not be used, as a means to circumvent or avoid the benefit limits established by the bureau of TennCare. It is expected that these applications will be submitted to address special, unforeseen, or exceptional circumstances. Such applications must be submitted by a licensed medical provider who is treating the enrollee and shall request the provision of medically necessary health care services recommended or prescribed by the enrollee's treating provider that are beyond the scope of benefits provided through the TennCare program benefit package for which the enrollee is eligible. For the purposes of this subsection, "beyond the scope of benefits" means a benefit that is covered within limits by TennCare but for which the enrollee has exceeded the covered limits of that benefit. It does not include benefits that are not covered to any extent under TennCare for the applicant. The Foundation will not consider matters of eligibility for the TennCare program. Through its authority to promulgate rules and regulations, the bureau of TennCare will identify the parameters of this component of the TennCare Safety Net program, including the process for making application to this Foundation, which enrollees are eligible to apply, and a mechanism for determining which applications will be reviewed by the Foundation. The Foundation will not have rule-making authority.

(C) (i) Notwithstanding the availability of assistance from the Foundation, no enrollee has an expectation of or an entitlement to assistance from the Foundation.

(ii) There exists no right of appeal regarding an application for assistance.

(iii) Because the level of funding provided to the Foundation is limited, the Foundation may not be able to fully or partially fund all applications. The decisions of which applications to fund will be solely within the discretion of the Foundation.

(D) Nothing in this subsection shall be construed to require a contested case hearing as set forth in the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, nor shall any determinations made by the Foundation be considered final orders from which appeals can be taken. The consideration of applications provided for by this subdivision shall not constitute hearings as set forth in the Uniform Administrative Procedures Act.

(E) The Foundation shall consider applications and determine in its sole discretion and without requirement for written findings whether the application should be granted in whole or in part. The Foundation's determination on an enrollee's application shall have no binding precedential effect on the consideration of any other enrollees' applications.

(F) In the event that a matter being considered by the Foundation presents a real or apparent conflict of interest for any staff or member, such staff or member shall disclose the conflict to the chair and recuse himself or herself from any official action taken on the matter.

(G) Notwithstanding the provisions of Tennessee Code Annotated, Section 8-44-101, et seq., or any other law to the contrary, any and all meetings of the TennCare Foundation are to be considered confidential and closed to the public. Members and staff shall maintain strict standards of confidentiality in the handling of all matters before the Foundation. In addition, all relevant Federal and State laws regarding patient privacy and confidentiality will be adhered to. All material and information, regardless of form, medium, or method of communication, provided to or acquired by a Foundation member or staff in the course of the Foundation's work, shall be regarded as confidential information, shall not be disclosed, and are not public records. In addition, all material and information, regardless of form, medium, or method of communication, made or generated by a member or Foundation staff in the course of the Foundation's work, shall be regarded as confidential information and shall not be disclosed and are deemed not to be a public record. All necessary steps shall be taken by members and staff to safeguard the confidentiality of such material or information in conformance with Federal and State law.

(H) Every October 1, the Foundation shall report in writing to the Governor, the TennCare Oversight Committee, the General Welfare, Health and Human Resources Committee of the Senate, the Health and Human Resources Committee of the House of Representatives, and the Commerce Committees of the General Assembly how funds allocated to the Foundation were spent during the previous fiscal year. Such report shall contain the following information:

(i) how many applications were received;

(ii) how many applications the Foundation granted;

(iii) the type of services and items that were funded; and

(iv) statistical information, by gender, race, and division of the State, on who applied for and who received the funds.

(I) Whether members shall receive reasonable compensation for their service on the TennCare Foundation will be determined at the discretion of the Governor; members may be reimbursed for those expenses allowed by the provisions of the comprehensive travel regulations promulgated by the Department of Finance and Administration and approved by the Attorney General.

(J) If any federal or state court or other tribunal with jurisdiction:

(1) determines that any aspect of subdivisions (A), (B), (C), (D), (E), or (G) of this subsection (f)(2) violates federal law, state law, or any existing court order or consent decree, and

(2) makes effective an order enjoining compliance with any aspect of these provisions or requiring non-trivial changes in the terms or applications of these provisions,

the challenged provisions may not be severed from the remainder of this subsection (f)(2). In this event, all provisions of this subsection (f)(2) will terminate and have no further effect. Such termination shall occur no later than ninety (90) days after the effective date of the order unless such order is stayed by the issuing court or the reviewing court pending disposition of an appeal of the order. The decision whether or not to appeal any such order will be at the sole discretion of the bureau of TennCare. This non-severability provision shall be self-executing. If the provisions of this subsection (f)(2) are terminated while appropriated funds remain, the unused funds shall revert back to the general fund. Any payments for services or items which have been approved but not yet disbursed as of the date of termination shall be paid, but no further applications for payments shall be considered or granted after the date of termination. In the event of termination under this provision, the Foundation may be reinstated only by new legislative action and a new appropriation by the General Assembly.

(g) The bureau of TennCare shall have the authority, in collaboration with one or more medical schools located in Tennessee, to establish an evidence-based medicine initiative for the purpose of developing medical protocols and integrating standards of best practice within the delivery of TennCare services. To the extent that evidence-based medical protocols are authorized by the bureau of TennCare, such protocols shall satisfy the standard of medical necessity as set forth in Section 22 of this Act. The bureau of TennCare, through its authority to promulgate rules and regulations, shall establish the parameters for the initiative, including who can participate and how the initiative is to be implemented.

SECTION 3. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following language as a new appropriately designated section:

Section ____: (a) There is established in the Department of Finance and Administration a TennCare Advisory Commission. The Advisory Commission will be separate and distinct from the bureau of TennCare but will be allowed access to all data concerning the operations, management, and program functions of the TennCare program, including information relevant to the TennCare program held or maintained by other state agencies. In accordance with 45 CFR Section 160.101, et seq., members of the Advisory Commission will provide non-paid consulting services to the bureau of TennCare and may have access to protected health information to the extent necessary to perform their advisory function.

(b) The Advisory Commission shall be appointed by the Governor and will be composed of eleven members who should reflect the broad impact that the TennCare program has on the State of Tennessee. The membership of the Advisory Commission

shall include one representative of the advocacy community, two representatives from the Tennessee business community, and three representatives from the provider community.. In addition, the membership of the Advisory Commission shall include one (1) person chosen by the Governor from a list of three (3) persons nominated by the Speaker of the House of Representatives, and one (1) person chosen by the Governor from a list of three (3) persons nominated by the Speaker of the Senate. If the Governor does not choose a commissioner member from the initial list of three (3) persons nominated by each speaker, the appropriate speaker shall submit another list of three (3) persons for the Governor's consideration. In making the appointments, the Governor shall strive to ensure that the Advisory Commission's membership is representative of the state's geographic and demographic composition with appropriate attention to the representation of women and minorities. In making the initial appointments, the Governor will designate three initial appointees to serve until December 31, 2005, four initial appointees to serve until December 31, 2006, and four initial appointees to serve until December 31, 2007. Except for initial appointments, members shall be appointed to three-year terms. At the time of the initial appointments of the Advisory Commission, the Governor shall appoint a chair and vice-chair of the Commission from the membership of the Commission who shall serve until December 31, 2005. The Governor shall thereafter appoint a chair and vice-chair to one year terms from the membership of the Commission.

(c) The purpose of the Commission is annually to review the health care operations, including but not limited to, cost-management analysis, benefits, enrollment, eligibility, costs, and performance, of the TennCare program and to make recommendations to the Governor regarding cost-containment strategies and cost-effective program improvements. Such recommendations by the Commission will include an assessment of the effectiveness of the existing TennCare program, specific steps that could be taken to reduce program costs, and an evaluation of whether the program is optimizing its use of resources to best meet the needs of TennCare enrollees. Proposed modifications submitted by the Commission that may result in increased program expenditures should be accompanied by recommendations to achieve commensurate savings in other program areas in order to achieve overall management of program costs. The Commission shall present its recommendations in writing to the Governor no later than November 10 of each year.

(d) Subject to an appropriation set forth in the General Appropriations Act, the Commission will have the power to engage expert assistance, in accordance with state procurement processes. The Department of Finance and Administration will provide the Commission with appropriate staff and assistance.

(e) Members of the Advisory Commission shall maintain strict standards of confidentiality in the handling of all matters before the Commission in accordance with Federal and State law. All material and information, regardless of form, medium, or method of communication, provided to or acquired by a member or the Commission staff in the course of the Commission's work, shall be regarded as confidential information and shall not be disclosed and are deemed not to be a public record. In addition, all material and information, regardless of form, medium, or method of communication, made or generated by a member or the Commission staff in the course of the Commission's work, shall be regarded as confidential information and shall not be disclosed and are not public records. All necessary steps shall be taken by members

and staff to safeguard the confidentiality of such material or information in conformance with Federal and State law.

(f) Items or matters discussed by the Commission may from time to time present real or apparent conflicts for members of the Commission. Due to the importance of the Commission's work and the advisory nature of its recommendations, in the event that a matter being considered by the Commission presents a real or apparent conflict of interest, the affected member of the Commission shall disclose the conflict to the chair but shall be allowed to discuss and take official action on the particular matter. The professional backgrounds of each member of the Advisory Commission as well as any conflicts disclosed by a member to the chair during a given year shall be reported in the Commission's recommendations as set forth in subsection (c) of this section.

(g) Members shall receive no compensation for their services on the Commission but may be reimbursed for those expenses allowed by the provisions of the comprehensive travel regulations promulgated by the Department of Finance and Administration and approved by the Attorney General and Reporter.

SECTION 4. Tennessee Code Annotated, Section 71-5-106(l) (1), is amended by deleting the subdivision in its entirety and substituting instead the following:

(1) All non-Medicaid eligible TennCare enrollees will have the responsibility to complete an eligibility process each year; in the absence of re-application and completion of the process, coverage will expire;

SECTION 5. Tennessee Code Annotated, Section 71-5-106(l) (2), is amended by deleting the subdivision in its entirety and substituting instead the following:

(2) Upon notification by the bureau of TennCare, the enrollee must submit application for continuation of eligibility within ninety (90) days; once an application has been timely submitted, the enrollee must provide all required documentation to verify continued eligibility in accordance with TennCare rules and regulations;

SECTION 6. Tennessee Code Annotated, Section 71-5-106(l) (4), is amended by deleting the subdivision in its entirety and substituting instead the following:

(4) Lack of receipt of the notification does not excuse the responsibility of the enrollee to submit an application and provide documentation for continuation of eligibility as required by TennCare rules and regulations if the enrollee has changed address and failed to notify the bureau of TennCare or its designee; and

SECTION 7. Tennessee Code Annotated, Section 71-5-106(o), is amended by deleting the subsection in its entirety and substituting instead the following:

(o) Except as may be required by federal law or the TennCare waiver, no person shall be eligible to receive TennCare benefits (except employee health insurance subsidy payments) as part of the TennCare waiver expansion population if such person is enrolled in a health insurance plan as such coverage is defined in TennCare rules and regulations, or if such person is eligible for participation in Medicare or group health insurance offered through an employer or family member's employer, or COBRA coverage.

SECTION 8. Tennessee Code Annotated, Section 71-5-106(p), is amended by deleting the subsection in its entirety and substituting instead the following:

(p) All determinations of eligibility for persons medically eligible as uninsurable in the TennCare waiver's expansion population shall be made on the basis of health conditions which prevent the person from obtaining health insurance. Such a determination will be based upon a review of medical records and information in accordance with TennCare rules and regulations.

SECTION 9. Tennessee Code Annotated, Section 71-5-110(b), is amended by deleting the period (".") at the end of the third sentence and substituting instead the following:

or, if the individual's business is newly established, documentation deemed sufficient by the bureau of TennCare or the Department of Human Services to project self-employment earnings pending completion of the upcoming year's income tax return.

SECTION 10. Tennessee Code Annotated, Section 71-5-118, is amended by deleting in the first sentence of subsection (a) the word "health" and substituting instead the words "Finance and Administration" and is further amended by deleting in subsection (k) the words "and enrollee fraud and abuse" and is further amended by deleting subsections (b), (c), (d), (e), (f), (g), (h), and (j) in their entirety and redesignating the remaining subsections accordingly.

SECTION 11. Tennessee Code Annotated, Sections 71-1-401, 71-1-402, 71-1-403, 71-1-404, 71-1-405, and 71-1-406, are amended by deleting them in their entirety.

SECTION 12. Tennessee Code Annotated, Section 71-5-197, is amended by deleting subsection (b) in its entirety and by substituting instead the following:

(b) The bureau of TennCare is authorized to implement, either independently or in combination with a state preferred drug list (PDL), cost saving measures for pharmaceutical services, including but not limited to, tiered co-payments, reference pricing, prior authorization and step therapy requirements; provided, however, that any prior approval process shall, at a minimum, comply with the provisions of 42 U.S.C. Section 1396r-8(d)(5), the provisions of which require a response to a request for prior authorization within twenty-four (24) hours and further require at least a seventy-two (72) hour supply of a covered outpatient drug in an emergency situation.

SECTION 13. Tennessee Code Annotated, Section 71-5-197, is amended by deleting subsection (c) in its entirety and by substituting instead the following:

(c) The bureau of TennCare, through a state pharmacy benefit manager (PBM) or on its own, is authorized to negotiate supplemental manufacturer rebates for TennCare prescription drug purchases; provided, however, that when conducting such negotiations, the bureau and/or PBM shall utilize the average manufacturer's price (AMP) as defined in 42 U.S.C. Section 1396r-8(k)(1) or any other recognized acceptable basis for negotiating rebates as the cost basis for the product.

SECTION 14. Tennessee Code Annotated, Section 71-5-198, is amended by deleting subsection (c) in its entirety and by substituting instead the following:

(c) To the extent permitted by federal law and the TennCare waiver, the bureau of TennCare may implement, either independently or in combination with a state preferred drug list (PDL), cost saving measures for pharmaceutical services, including but not limited to, tiered co-payments, reference pricing, prior authorization, step therapy requirements, exclusion from coverage of drugs or classes of drugs, mandating the use of generic drugs, and mandating the use of therapeutic equivalent drugs.

SECTION 15. Tennessee Code Annotated, Section 71-5-198, is amended by adding the following as a new appropriately designated subsection:

(___) The bureau of TennCare may, in its sole discretion, adopt or amend a PDL. The adoption or amendment of a PDL, and the recommendations of the TennCare Pharmacy Advisory Committee to the bureau are not agency actions and do not require rulemaking.

SECTION 16. Tennessee Code Annotated, Section 71-5-2404, is amended by deleting subsection (a) in its entirety and by substituting instead the following:

(a) The TennCare pharmacy advisory committee shall submit to the bureau of TennCare both specific and general recommendations for drugs to be included on any state preferred drug list (PDL) adopted by the bureau. In making its recommendations, the committee shall consider factors, including but not limited to, efficacy, the use of generic drugs and therapeutic equivalent drugs, and cost information related to each drug. The committee shall also submit recommendations to the bureau regarding computerized, voice, and written prior authorization, including prior authorization criteria, and step therapy.

SECTION 17. Tennessee Code Annotated, Section 71-5-2404, is amended by deleting subsection (c) in its entirety and by substituting instead the following:

(c) TennCare or its designee shall provide the State TennCare Pharmacy Advisory Committee, the Office of TennCare Inspector General, and the State's Medicaid Fraud Control Unit with clinical and economic research and utilization information as requested on drugs and drug classes.

SECTION 18. Tennessee Code Annotated, Section 4-3-1013, is amended by deleting subsection (e) in its entirety and by substituting instead the following:

(e) To the extent permitted by federal law and the TennCare waiver, the bureau of TennCare may implement, either independently or in combination with a state preferred drug list (PDL), cost saving measures for pharmaceutical services, including but not limited to, tiered co-payments, reference pricing, prior authorization, step therapy requirements, exclusion from coverage of drugs or classes of drugs, mandating the use of generic drugs, and mandating the use of therapeutic equivalent drugs.

SECTION 19. Tennessee Code Annotated, Section 71-5-108, is amended by deleting the section in its entirety.

SECTION 20. Tennessee Code Annotated, Title 71, Chapter 5, is amended by adding a new Part 25 as follows:

SECTION _____. This part shall be known and may be cited as "The TennCare Fraud and Abuse Reform Act of 2004."

SECTION _____. There is created a division of state government which shall be known and designated as the Office of TennCare Inspector General. This division shall be located within the Department of Finance and Administration and shall report directly to the Commissioner of Finance and Administration. The Office of TennCare Inspector General shall be headed by an Inspector General. The Office of TennCare Inspector General shall be separate and distinct from the Medicaid Fraud Control Unit (MFCU).

SECTION _____. As used in this part unless the context otherwise requires:

(1) "Abuse" shall be given the same meaning as currently exists in federal regulations located at 42 CFR 455.2, with the following exceptions: (i) it shall also apply to practices by vendors or other persons or entities and (ii) it shall also apply to the TennCare program.

(2) "Applicant" means any person who has applied for benefits under title 71, chapter 5, part 1.

(3) "Benefits" means the health care package of services available to TennCare enrollees.

(4) "CMS" (Centers For Medicare and Medicaid Services) means the agency within the United States Department of Health and Human Services that is responsible for administering Title XVIII, Title XIX, and Title XXI of the Social Security Act.

(5) "Commissioner" means the Commissioner of Finance and Administration.

(6) "Department" means the Department of Finance and Administration.

(7) "Enrollee" shall mean an individual eligible for and enrolled in the TennCare program or in any successor Medicaid program in Tennessee.

(8) "Fraud" means an intentional deception or misrepresentation made by a person, including but not limited to, a vendor, recipient, provider, or enrollee, with the knowledge that the deception or misrepresentation could result in some unauthorized benefit or payment to himself or herself or some other person. It includes any act that constitutes fraud under applicable Federal or State law, including but not limited to, the Tennessee Medicaid False Claims Act.

(9) "Inspector General" means the person who directs the Office of TennCare Inspector General, who shall report directly to the Commissioner of Finance and Administration.

(10) "Medical assistance" means payment of the cost of care, services and supplies necessary to prevent, diagnose, correct or cure conditions in the person that cause acute suffering, endanger life, result in illness or infirmity,

interfere with the person's capacity for normal activity, or threaten some significant handicap and which are furnished an eligible person in accordance with the rules, regulations, and statutes governing TennCare. Such care, services and supplies includes services of qualified practitioners licensed under the laws of this State.

(11) "MFCU" means the Medicaid Fraud Control Unit.

(12) "Provider" shall mean an institution, facility, agency, person, corporation, partnership, or association providing benefits to a TennCare enrollee.

(13) "Recipient" means any person who has been determined eligible to receive benefits under title 71, chapter 5, part 1, and who has received such benefits.

(14) "TennCare" means the program administered by the Single State agency as designated by the State and CMS pursuant to Title XIX of the Social Security Act and the Section 1115 Research and Demonstration waiver granted to the State of Tennessee.

(15) "Vendor" means any person, institution, agency, or business concern providing medical care services or goods authorized under title 71, chapter 5, part 1, holding, where applicable, a current valid license to provide such services or to dispense such goods; or any health maintenance organization as defined in title 56, chapter 32, with which the State has entered into a contract based on a per capita rate of payment for services provided under title 71, chapter 5, part 1. The term "vendor" also means for purposes of this chapter a person, entity, institution, agency or business concern that, pursuant to contract with the State, manages care or otherwise administers TennCare services as an administrative services organization, pharmacy benefits manager or other managed care organization.

SECTION _____. The commissioner is authorized to promulgate rules and regulations, including public necessity rules pursuant to §4-5-209, to effectuate the purposes of this part. All such rules and regulations shall be promulgated in accordance with the provisions of the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION _____. The Office of TennCare Inspector General shall have the authority to:

(a) Investigate civil and criminal fraud and abuse of the TennCare program, or any other violations of state criminal law related to the operation of TennCare;

(b) Cooperate with the MFCU and where a preliminary investigation of fraud and abuse by a provider establishes a sufficient basis to warrant a full investigation, refer such matters to the MFCU;

(c) Refer matters to the appropriate enforcement authority for criminal prosecution;

(d) Refer matters to the appropriate enforcement authorities for civil proceedings, and assist in the recovery of funds which have been inappropriately paid by the TennCare program, including, but not limited to, referral to the Attorney General for civil recovery;

(e) Cooperate with the appropriate federal departments in any reasonable manner as may be necessary to qualify for federal aid in connection with TennCare;

(f) Cooperate with the federal government and other state governments to investigate TennCare and medicaid fraud and abuse;

(g) Cooperate with other state agencies to investigate TennCare and medicaid fraud and abuse;

(h) Within sixty (60) days after the close of each fiscal year, prepare and print a summary report, which shall be submitted to the Governor, members of the General Assembly, the TennCare Advisory Commission, the TennCare Oversight Committee of the General Assembly, and the Commissioner. This report shall include a summary of all activities of the Office of TennCare Inspector General during that fiscal year;

(i) Furnish information to acquaint the public with the fraud and abuse laws pertaining to TennCare;

(j) Contract with necessary entities to carry out the required duties of this part. All such contracts shall be procured in accordance with the requirements of title 12, chapter 4, part 1; and

(k) Exercise any additional powers necessary to carry out the purposes and provisions of this part.

SECTION _____. (a) The Office of TennCare Inspector General shall have the authority to provide legal assistance to the Attorney General and the State District Attorneys for the purpose of initiating and handling proceedings in appropriate TennCare fraud and abuse cases. Such assistance may include but not be limited to, the authority to fund Assistant Attorney General or Assistant District Attorney positions in those respective offices, subject to the appropriations made to the Office of TennCare Inspector General and the agreement of the offices concerned. The Office of TennCare Inspector General shall also have the authority to fund public defender positions, subject to the appropriations made to the Office of TennCare Inspector General and the agreement of the offices concerned. The Office of TennCare Inspector General may, with reasonable notice, terminate the funding of any attorney positions which the Inspector General has funded in either of these offices.

(b) Venue for civil actions involving fraud and abuse shall be in the county where the offense was committed or in Davidson County. Venue for criminal actions involving fraud and abuse shall be to the full extent permitted by the Constitution of the State.

SECTION _____. (a) The staff of the Office of TennCare Inspector General may include law enforcement officers, as defined in TCA §39-11-106(21) and qualified as defined in TCA §38-8-106, who have successfully completed a training course approved by the Tennessee peace officer standards and training commission, including surveillance training.

(b) Any duly authorized law enforcement officer who has been specifically designated by the Inspector General to enforce the provisions of this part is authorized and empowered to go armed while on active duty engaged in enforcing the provisions of this part. Any such person is also authorized and empowered to execute search warrants and do all acts incident thereto in the same manner as search warrants may be executed by sheriffs and other peace officers.

SECTION _____. There is established a "Medicaid Fraud Control Unit", which is separate and distinct from the state Medicaid agency, within the criminal investigation division of the Tennessee Bureau of Investigation or within another appropriate agency at the discretion of the Governor. As regulated by federal law, the unit is authorized to investigate and refer for prosecution violations of all applicable laws pertaining to provider fraud and abuse in the administration of the Medicaid program, the provision of medical assistance or the activities of providers of medical assistance under the state Medicaid plan; Medicare fraud; and abuse or neglect in healthcare facilities receiving payments under the state Medicaid plan, such as board and care facilities as allowed by federal law. A summary of the unit's work shall be included in a report which shall be submitted annually to the Governor and the Judiciary Committees of the General Assembly.

SECTION _____. (a)(1) The Office of TennCare Inspector General, when conducting any investigation relating to TennCare fraud or abuse, shall have the power to issue subpoenas, and compel the attendance of witnesses, the examination of such witnesses under oath, and the production of books, accounts, papers, records, and documents relating to such investigation.

(2) In the case of failure of any person, firm, or corporation so subpoenaed to attend or to produce the specified records, and after reasonable notice to such person, firm, or corporation, the Office of TennCare Inspector General may seek judicial enforcement of the subpoena by filing, through the Attorney General, a petition with the Circuit or Chancery court of Davidson County or of the judicial district in which such person, firm, or corporation resides. Such petition shall incorporate or be accompanied by a certification regarding the notice given and the failure of such person, firm or corporation to attend or produce the records.

(3) Upon the filing of such a petition in proper form, the court shall order the person, firm, or corporation named in the petition to appear and show cause why they should not comply with the subpoena or be held in contempt for failure to comply. The court shall have authority to employ all judicial power as provided by law to compel compliance with the subpoena, including those powers granted in Sections 29-9-103 through 29-9-106 of this code. The court shall be authorized to impose costs and sanctions against any such person, firm, or corporation, in the same manner and on the same bases as may be imposed for failure to comply with judicially issued subpoenas under the Tennessee Rules of Civil Procedure.

(4) The court may order the person, firm, or corporation to comply, and shall have the authority to punish each day of failure to comply with such order as a separate contempt of court.

(5) The subpoena enforcement remedies set forth in this section shall be cumulative, and not exclusive, of any other remedies provided by law for the enforcement of such subpoenas.

(b) The Office of TennCare Inspector General shall have the power to compel the production of current and former employment records during an investigation. Employment records include but are not limited to, employment details, wages, and insurance information of TennCare applicants and enrollees. Employment records shall be open to inspection and be subject to being copied by an Office of TennCare Inspector General representative at any reasonable time and as often as may be necessary. The Office of Inspector General shall also have the right to compare information reported to TennCare by applicants or enrollees with data maintained by the credit bureaus.

(c) The complete patient record of an enrollee or recipient generated during the TennCare enrollment period shall be made available to the Office of TennCare Inspector General upon request. This includes any and all services, goods and pharmaceuticals dispensed regardless of payment source. Access to these records under this section may occur during and after enrollment in the TennCare program. Records accessed during an investigation shall be protected in accordance with state and federal privacy laws.

SECTION 21. Tennessee Code Annotated, Section 10-7-504(a)(2), is amended by deleting the subdivision in its entirety and by substituting instead the following language:

(a)(2) All investigative records of the Tennessee Bureau of Investigation, the Office of TennCare Inspector General, all criminal investigative files of the motor vehicle enforcement division of the Department of Safety relating to stolen vehicles or parts, and all files of the handgun carry permit and driver license issuance divisions of the Department of Safety relating to bogus handgun carry permits and bogus driver licenses issued to undercover law enforcement agents shall be treated as confidential and shall not be open to inspection by members of the public. The information contained in such records shall be disclosed to the public only in compliance with a subpoena or an order of a court of record, however, such investigative records of the Tennessee Bureau of Investigation shall be open to inspection by elected members of the General Assembly if such inspection is directed by a duly adopted resolution of either house or of a standing or joint committee of either house. Records shall not be available to any member of the executive branch except to the Governor and to those directly involved in the investigation in the Tennessee Bureau of investigation and in the Office of TennCare Inspector General. The Tennessee Bureau of Investigation, upon written request by an authorized person of a state governmental agency, is authorized to furnish and disclose to the requesting agency the criminal history, records and data from its files, and the files of the federal government and other states to which it may have access, for the limited purpose of determining whether a license or permit should be issued to any person, corporation, partnership or other entity, to engage in an authorized activity affecting the rights, property or interests of the public or segments thereof.

SECTION 22. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following language as a new appropriately designated section:

Section _____. (a) Enrollees under the TennCare program are eligible to receive, and TennCare shall provide payment for, only those medical items and services that are:

(1) within the scope of defined benefits for which the enrollee is eligible under the TennCare program; and

(2) determined by the TennCare program to be medically necessary.

(b) To be determined to be medically necessary, a medical item or service must be recommended by a physician who is treating the enrollee or other licensed healthcare provider practicing within the scope of his or her license who is treating the enrollee and must satisfy each of the following criteria:

(1) It must be required in order to diagnose or treat an enrollee's medical condition. The convenience of an enrollee, the enrollee's family, or a provider, shall not be a factor or justification in determining that a medical item or service is medically necessary;

(2) It must be safe and effective. To qualify as safe and effective, the type and level of medical item or service must be consistent with the symptoms or diagnosis and treatment of the particular medical condition, and the reasonably anticipated medical benefits of the item or service must outweigh the reasonably anticipated medical risks based on the enrollee's condition and scientifically supported evidence;

(3) It must be the least costly alternative course of diagnosis or treatment that is adequate for the medical condition of the enrollee. When applied to medical items or services delivered in an inpatient setting, it further means that the medical item or service cannot be safely provided for the same or lesser cost to the person in an outpatient setting. Where there are less costly alternative courses of diagnosis or treatment, including less costly alternative settings, that are adequate for the medical condition of the enrollee, more costly alternative courses of diagnosis or treatment are not medically necessary. An alternative course of diagnosis or treatment may include observation, lifestyle or behavioral changes or, where appropriate, no treatment at all; and

(4) It must not be experimental or investigational. A medical item or service is experimental or investigational if there is inadequate empirically-based objective clinical scientific evidence of its safety and effectiveness for the particular use in question. This standard is not satisfied by a provider's subjective clinical judgment on the safety and effectiveness of a medical item or service or by a reasonable medical or clinical hypothesis based on an extrapolation from use in another setting or from use in diagnosing or treating another condition.

(A) Use of a drug or biological product that has not been approved under a new drug application for marketing by the United States Food and Drug Administration (FDA) is deemed experimental.

(B) Use of a drug or biological product that has been approved for marketing by the FDA but is proposed to be used for other than the FDA-approved purpose will not be deemed medically necessary unless the use can be shown to be widespread, to be generally accepted by the professional medical community as an effective and proven treatment in the setting and for the condition for which it is used, and to satisfy the requirements of (b)(1)-(3).

(c) It is the responsibility of the bureau of TennCare ultimately to determine what medical items and services are medically necessary for the TennCare program. The fact that a provider has prescribed, recommended or approved a medical item or service does not, in itself, make such item or service medically necessary.

(d) The medical necessity standard set forth in this section shall govern the delivery of all services and items to all enrollees or classes of beneficiaries in the TennCare program. The bureau of TennCare is authorized to make limited special provisions for particular items or services, such as long-term care, or such as may be required for compliance with federal law.

(e) Medical protocols developed using evidence-based medicine that are authorized by the bureau of TennCare pursuant to Section 2 of this act shall satisfy the standard of medical necessity. Such protocols shall be appropriately published to all TennCare providers and managed care organizations.

(f) The bureau of TennCare is authorized to promulgate such rules and regulations as may be necessary to implement the provisions of this section.

SECTION 23. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following as a new appropriately designated section:

Section _____. (a) Notwithstanding any other provision of law to the contrary, any initiative, program or measure operated by the bureau of TennCare, including but not limited to, disease management programs, may require enrollees to obtain prescription drugs, durable medical equipment, or medical supplies in such manner as the bureau of TennCare determines to be the most cost-effective.

(b) The bureau of TennCare shall consult with Tennessee pharmacists who are providers actively participating in the TennCare pharmacy program in making a determination of cost effectiveness of any proposed pharmacy program.

SECTION 24. Tennessee Code Annotated, Section 53-10-304(c), is amended by deleting the subsection in its entirety and by substituting instead the following language:

(c) The purpose of the database is to assist in research, statistical analysis and the education of health care practitioners concerning patients who, by virtue of their conduct in acquiring controlled substances, may require counseling or intervention for substance abuse, by collecting and maintaining data as described in this part regarding

all controlled substances in Schedules II, III and IV dispensed in this State, and Schedule V controlled substances identified by the controlled substance database advisory committee as demonstrating a potential for abuse.

SECTION 25. Tennessee Code Annotated, Section 53-10-304(d), is amended by deleting the subsection in its entirety and by substituting instead the following language:

(d) The data required by this part shall be submitted in compliance with this part to the committee by any practitioner, or person under the supervision and control of the practitioner, pharmacist or pharmacy who dispenses a controlled substance contained in Schedules II, III and IV, and Schedule V controlled substances identified by the controlled substance database advisory committee as demonstrating a potential for abuse. The reporting requirement shall not apply for the following:

(1) A drug administered directly to a patient;

(2) Any drug dispensed by a licensed health care facility provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours;

(3) Any drug sample dispensed; or

(4) Any facility that is registered by the United States Drug Enforcement Administration as a narcotic treatment program and is subject to the recordkeeping provisions of 21 CFR 1304.24.

SECTION 26. Tennessee Code Annotated, Section 53-10-305(b), is amended by deleting the subsection in its entirety and by substituting instead the following language:

(b) A pharmacy dispenser that uses a computerized system to record information concerning the dispensing of controlled substances listed in Schedule II, III, or IV, and Schedule V controlled substances identified by the controlled substance database advisory committee as demonstrating a potential for abuse, shall submit the required information to the committee or its agent utilizing nationally recognized pharmacy telecommunications format standards.

SECTION 27. Tennessee Code Annotated, Section 53-10-306(a), is amended by adding the following new subsection thereto:

(5) Personnel actively engaged in analysis of controlled substances prescription information as a part of their assigned duties and responsibilities related directly to TennCare of the following entities:

(A) The office of TennCare Inspector General;

(B) The Medicaid Fraud Control Unit; and

(C) The Tennessee Bureau of Investigation.

SECTION 28. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following as a new appropriately designated section:


Section _____. On and after July 1, 2004, the bureau of TennCare, through its authority to promulgate rules and regulations, may implement and maintain a pharmacy lock-in program designed to address member abuse, overutilization and quality of care concerns for TennCare enrollees.

SECTION 29. To effectuate the provisions of this act, the Commissioner of Finance and Administration shall have the authority to promulgate any necessary rules and regulations not otherwise provided for in this act. All rules and regulations provided for in this act are authorized to be promulgated as public necessity rules pursuant to §4-5-209. All such rules and regulations shall be promulgated in accordance with the provisions of the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 30. Except as specifically provided in Section 2 of this act, if any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

SECTION 31. This act shall take effect upon becoming a law, the public welfare requiring it.

PASSED: May 6, 2004


JIMMY NAIFEH, SPEAKER
HOUSE OF REPRESENTATIVES


JOHN S. WILDER
SPEAKER OF THE SENATE

APPROVED this 17th day of May 2004


PHIL BREDESEN, GOVERNOR